Selector® Quantum Ultrasonic Surgical Aspirator System

510(k) Summary

August 20, 2004

A. Submitter Information

Manufacturer
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Contact Person: Nancy Mathewson
Director, Regulatory Affairs
E-Mail: nmathewson@integra-ls.com

B. Device Identification

Proprietary Name: Selector® Quantum Ultrasonic Surgical Aspirator System
Common Name: Ultrasonic Surgical Aspirator
Classification Name: Instrument, Ultrasonic Surgical
Code: 192 LFL
Classification Panel: General and Plastic Surgery

C. Identification of Predicate Devices

The Selector® Quantum Ultrasonic Surgical Aspirator System is substantially equivalent to the following previously cleared and currently marketed devices:

- Selector® Ultrasonic Surgical Aspirator System (K901974, K925129, K021989)
- CUSA Excel Ultrasonic Surgical Aspirator System (K981262)
- Sonopet UST 2001 Ultrasonic Surgical Aspirator System (K010309)

D. Intended Use

The SELECTOR® Quantum Ultrasonic Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery.

E. Device Description

The SELECTOR® Quantum Ultrasonic Aspirator System dissects and fragments soft tissue and leaves essential elastic structures such as nerves and blood vessels relatively undamaged. It is particularly useful for the ablation of unwanted tissue adjacent or attached to vital structures.

The system consists of a Console, which provides control and display of aspiration, irrigation and ultrasonic power, and one or more Handpieces for selective tissue removal at the surgical site. The handpieces have a titanium tip and silicone irrigation flue. The tips are interchangeable which allows the surgeon to use the same handpiece for different applications. The required settings on the Console are selected by operation of up-down controls on the front panel. The Console provides power to the footswitch, which has two controls. One pedal provides proportional control of ultrasonic power, and the other the flow of irrigation fluid. An accessory Service Module may be used to provide a convenient source of suction and waste collection.

A range of handpieces are connected to the console, both electrically and by a disposable sterile tubing kit which delivers sterile saline for irrigation, and removes aspirated waste matter. A special version of the Selector system will be available for use within an MRI suite. All handpieces may be sterilized by steam autoclaving or by Ethylene Oxide.

The Selector® Quantum Ultrasonic Aspirator System described in the submission is a modification of the Selector® Integra Ultrasonic Surgical Aspirator System currently cleared to market. The main differences are that the Selector® Quantum Ultrasonic Surgical Aspirator System has:

- a software user interface on a LCD display screen
- a new range of handpieces with interchangeable tips
- pulse mode
- a more powerful vacuum system for enhanced aspiration

The Indications for Use and all other aspects of the device remain the same.

F. Safety and Performance Data

The Selector® Quantum Ultrasonic Surgical Aspirator System has been designed to conform to the following standards, as applicable:

CSA22.2 No. 601-1
EN 60601-1
EN60601-1-2
EN60601-2-2
FCC 18
JIS T 1001/1002
UL 2601-1

The footswitch is additionally rated IP2.7 for dust and moisture resistance.

The Selector® Quantum handpieces will be tested to comply to ISO 11134:1994 for steam sterilisation and ISO 11135:1994 for ethylene oxide sterilisation.

The biological safety of the Selector® Quantum handpieces has been assured through the selection of materials that demonstrate appropriate levels of biocompatibility. The material is the same used in the current Selector® Integra handpieces and the Cusa Excel predicate. This material has been tested to ISO10993-1 and confirmed.

In addition, the Selector® Quantum was subjected to extensive performance testing. Results of the testing showed that the system design was technically sound and the product safe for its intended use.

The Selector® Quantum manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

G. Summary of Substantial Equivalence

The Selector Ultrasonic Surgical Aspirator System (Console, Handpieces and Accessories) is substantially equivalent in function, technical specifications, performance and intended use to the following predicates:

- Selector® Ultrasonic Surgical Aspirator System (K901974, K925129, K021989)
- CUSA Excel Ultrasonic Surgical Aspirator System, frequency 23kHz and 36kHz (K981262)
- Sonopet UST2001 Ultrasonic Surgical Aspirator, frequency 25 kHz/ 34kHz (K010309)

Table 1 is a feature comparison chart regarding the subject of this Premarket Notification for the SELECTOR® Quantum Ultrasonic Aspirator (previously cleared to marked under 510(k)s K901974, K925129 and K021989) and the predicate devices.

TABLE 1	*SELECTOR®* *INTEGRA* *K901974,* K925129 and K021989	CUSA Excel K981262	Sonopet UST 2001 K010309	*SELECTOR®* QUANTUM
Indications for Use	Neuro Gastro Uro Plastic & Recon. General Ortho Gynecology Thoracic Laparoscopic Thoracoscopic	Neuro Gastro Uro Plastic & Recon. General Ortho Gynecology Thoracic Laparoscopic Thoracoscopic	Neuro Gastro Uro Plastic & Recon. General Ortho Gynecology Thoracic Laparoscopic Thoracoscopic	Neuro Gastro Uro Plastic & Recon. General Ortho Gynecology Thoracic Laparoscopic Thoracoscopic
Basic Operating Principle Ultrasonic action through Titanium Alloy Tip onto biological tissue causes fragmentation and cavitation of tissue. Irrigation system bathes site, aspiration removes unwanted ablated tissue.				
Where used	Hospitals	Hospitals	Hospitals	Hospitals
Vibration System	Piezo	Magnetostrictive	Piezo	Piezo
Frequency	24 kHz & 35 kHz	23 kHz & 36 kHz	25 kHz & 34 kHz	24 kHz & 35 kHz
Irrigation Flow	0-50 ml/min	1-29 cc/min	3-<10ml/min	0-40 ml/min
Aspiration Vacuum	0-600 mmHg	0-660 mmHg	0-500 mmHg	0-700 mmHg
Tip Amplitudes	Max 24 kHz:305μm Max 35 kHz:215μm	Max 23 kHz:355μm Max 36 kHz:210μm	Max 350μm	Max 24 kHz:330μm Max 35 kHz:240μm
Materials in contact with tissue	TiAl6V4 Titanium Alloy	TiAl6V4 Titanium Alloy	Not known	TiAl6V4 Titanium Alloy
Power Source	100-240V 50/60Hz	110V 60Hz	100 - 200V 50/60Hz	100-240V 50/60Hz
Sterility	Steam EtO	Steam	Steam EtO	Steam EtO
Electrical Safety Standards Met	CSA 22.2 No. 601-1 60601-1 60601-1-2 FCC 18 JIS T1001/1002 UL2601-1	IEC 601-1 601-2-2 60601-1-2 CSA 22.2	Not known	CSA 22.2 No. 601-1 60601-1 60601-1-2 FCC 18 JIS T1001/1002 UL2601-1

Conclusion:

The SELECTOR® Quantum Ultrasonic Surgical Aspirator System is a modification of the SELECTOR® Integra Ultrasonic Surgical Aspirator System, previously cleared to market under 510(k) K901974, K925129 and K021989. It dissects and fragments soft tissue and leaves essential elastic structures such as nerves and blood vessels relatively undamaged. It is particularly useful for the ablation of unwanted tissue adjacent or attached to vital structures.

The Selector® Quantum Ultrasonic Surgical Aspirator System (Console, Handpieces and Accessories) is substantially equivalent in function, technical specifications, performance and intended use to the following predicate devices delineated in this submission:

- Selector® Integra Ultrasonic Surgical Aspirator System, frequency 24kHz and 35kHz, FDA 510(k) # K901974, K925129 and K021989
- CUSA Excel Ultrasonic Surgical Aspirator System, frequency 23kHz and 36kHz, FDA 510(k) #K981262K010309
- Sonopet UST2001 Ultrasonic Surgical Aspirator, frequency 25kHz and 34kHz, FDA 510(k) #

All predicates are used for similar applications in the medical field to those proposed for the SELECTOR® Quantum Ultrasonic Surgical Aspirator.

The SELECTOR® Quantum Ultrasonic Surgical Aspirator System meets the requirements for a Premarket Notification 510(k) as defined in CFR 21, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2004

Ms. Nikki Hinton
Quality Assurance/Regulatory Affairs Manager
Integra NeuroSciences Ltd.
Newbury Road
Andover, Hampshire SP10 4DR
UK

Re: K042277
Trade/Device Name: SELECTOR® Quantum Ultrasonic Surgical Aspirator
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 20, 2004
Received: August 23, 2004

Dear Ms. Hinton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number: K042277

Device Name: **SELECTOR® Quantum Ultrasonic Surgical Aspirator**

Indications for Use:

The SELECTOR® Quantum Ultrasonic Aspirator System is indicated for use in surgical procedures where fragmentation emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X__ (Per 21 CFR 801.109) Or Over-the-Counter Use ____ (Optional Formal 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042277